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10/500,756	04/08/2005	Karla Araujo	033794/280375	6840

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EXAMINER	
FRAZIER, BARBARA S	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,756	ARAUJO ET AL.	
	Examiner	Art Unit	
	BARBARA FRAZIER	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4 and 8-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4 and 8-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1, 2, 4, and 8-15 are pending in this application.

2. Claims 1, 2, 4, and 8-15 are examined.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. **Claims 1, 4, 8, and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lukenbach et al (US Patent 5,980,871).**

The claimed invention is drawn to an oily dispersion of pigments comprising zinc oxide and titanium dioxide added in the form of a powder to a single oily base in the amounts specified in claim 1, and further comprising a single emollient vehicle (see claim 1).

Lukenbach et al. disclose sunscreen compositions comprising an inorganic sunscreen compound, such as a mixture of titanium dioxide and zinc oxide, in an oil component comprising a carrier oil and at least one emollient (see col. 4, lines 28-37). The inorganic sunscreen compound is oil dispersible (col. 6, lines 34-36), and is added to the oil phase (col. 7, lines 30-34). The amount of titanium dioxide present in the composition is from about 2% to about 25% (col. 6, lines 27-30), and 5% zinc oxide is exemplified (Example 96, col. 13, lines 13-15).

Lukenbach et al do not teach a concentration of titanium dioxide from 30% to 35% by weight.

However, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to adjust the amount of titanium dioxide to 30%; thus arriving at the claimed invention. One skilled in the art would have been motivated to do so because Lukenbach et al's teaching of the amount "about 25%" is comparable to Applicant's teaching of the amount of 30%, especially given that the prior art uses the flexible modifier "about". It would have been obvious to determine workable and/or optimal amounts of pigment per the reasoning of well-established precedent, such as In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235(CCPA 1955). (Holding that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.")

Regarding claim 4, Lukenbach et al. teach that titanium dioxide is present in the final composition in an amount of about 2% to about 25% (col. 6, lines 29-30) and that zinc oxide is present in an amount of 5% by weight (col. 13, lines 14-15). This appears to be comparable to the amounts claimed by Applicants, especially given that the prior art uses the flexible modifier "about". In any case, it would have been obvious to determine workable and/or optimal amounts of pigment per the reasoning of well-established precedent, such as In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235(CCPA 1955). (Holding that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.")

Regarding claim 8, Lukenbach et al. teach that zinc oxide is present at 5% (Example 96, col. 13, lines 13-15). This is encompassed by Applicant's amount of 5 to 10%.

Regarding claim 13, Lukenbach et al. teach that the emollient should be present in the formulation in a ratio to the carrier concentration of from about 1:1 to about 3:1, most preferably about 2:1. This appears to be comparable to the amounts claimed by Applicants, i.e., where the weight percentage **within the oily dispersion** is 45-65%, especially given that the prior art uses the flexible modifier "about". In any case, it would have been obvious to determine workable and/or optimal amounts of emollient per the reasoning of well-established precedent, such as In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). (Holding that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.")

Regarding claim 14, Lukenbach et al teach the concurrent addition of the oil and emollient, followed by addition of titanium dioxide (see col. 7, lines 44-53). Lukenbach et al teach that both titanium dioxide and a mixture of titanium dioxide and zinc oxide are examples of the "inorganic sunscreen agent". Therefore, a person having ordinary skill in the art at the time the invention was made would have been motivated to substitute the mixture of titanium dioxide and zinc oxide for the titanium dioxide in the process outlined in Lukenbach et al, with a reasonable expectation of success.

Regarding claim 15, Lukenbach et al teach that "The compositions of this invention can be incorporated into various cosmetic and personal care products such as

hand and body lotions, oils, ointments, lip balm products, facial cosmetics and the like" (col. 7, lines 11-15).

Response to Arguments

5. Applicant's arguments filed 5/12/09 have been fully considered but they are not persuasive.

Applicants argue that the term "about" in the specification of Lukenbach should be limited to 25% or less, and should not be interpreted to disclose or suggest a range approaching 30% or greater. Applicants argue that the preferred amounts of Lukenbach are from about 2 to about 15%, and more preferably about 3 to about 10%, and therefore Lukenbach actually teaches a concentration that is significantly less than 25%. Applicants also argue that, because Lukenbach teaches that higher concentrations of titanium dioxide may be used, even up to 15%, or possibly higher, one of ordinary skill in the art would interpret anything above this range as "pure speculation". Applicants further argue that none of the examples of Lukenbach have a TiO_2 concentration above 15%, and most of the examples are not greater than 4.5%.

This argument is not persuasive because Lukenbach specifically teaches that its instant sunscreen compositions may contain amounts of sunscreen of "about 25%", which reasonably reads on 30%. As stated previously, a weight percent difference of 5% (from 25% to 30%) is considered to reasonably fall within the range of "about 25%". Applicant's assertions that the teaching of Lukenbach wherein the amount of titanium dioxide is "even up to 15% with acceptable appearance, or possibly higher" is not conclusive that anything above said range are "pure speculation"; on the contrary,

Lukenbach's teaching of possibly higher than 15% would indicate to one skilled in the art that amounts higher than 15%, such as "about 25%" would be useful in the invention of Lukenbach. In response to Applicant's arguments that the examples of Lukenbach do not teach amounts of titanium dioxide approaching 25%, it is noted that disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971).

Applicants also disagree with the statement that a weight percent difference of 5% (from 25% to 30%) is considered to reasonably fall within the range of "about 25%", and assert that the percent difference is actually 18.2%.

This argument is not persuasive because the weight percent difference is with respect to the total weight of the composition, not the total weight of the TiO_2 itself; therefore, the weight percent difference is from 25% to 30%, or 5%, as stated previously. An amount of 30% reasonably falls within the range of "about 25%"; therefore, one skilled in the art would be motivated to manipulate the amount of titanium dioxide from within said range by routine experimentation, in order to optimize the efficacy of the resultant composition.

In response to Applicant's argument that the Examiner has failed to provide any technical evidence or rational showing why the difference between 25% and 30% would be obvious, it is noted that a *prima facie* case of obviousness has been established for reasons stated above (i.e., that a weight amount of 30% reasonably falls within the

range of "about 25%"), and Applicants have failed to show the criticality of the amount of TiO_2 recited in the claimed invention.

Therefore, it is the Examiner's opinion that the claims are rendered obvious.

6. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lukenbach et al (US patent 5,980,871) in further view of Choulot et al (US 2004/0191189).

Claim 9 of the claimed invention is drawn to an oily dispersion of pigments for protection against UV radiation, characterized by comprising, in a single oily base, zinc oxide and titanium dioxide added in the form of a powder, wherein the two pigments are dispersed in a single oily dispersing vehicle and the dispersion further comprises a single emollient vehicle, and wherein the particle size of the TiO2 and ZnO pigments used ranges from 15 to 100 nanometers.

Lukenbach et al. teach that titanium dioxide should be used having a primary particle size from of less than about 300 nm in diameter (col. 6, lines 27-29).

Choulot et al. teach that it is known to use a mixture of titanium dioxide and zinc oxide with a mean particle size being between 1 and 100 nanometers in a sunscreen composition (page 1, paragraph 4).

Lukenbach et al. differ from the claimed invention in claim 9 because the reference is silent with respect to whether or not the mixture of titanium dioxide and zinc oxide is in particulate form (i.e., from 15 to 100 nanometers).

However, since Choulot et al. teach that it is known to use a mixture of titanium dioxide and zinc oxide with a mean particle size being between 1 and 100 nanometers in a sunscreen composition (page 1, paragraph 4), and since both compositions are sunscreen compositions, a person having ordinary skill in the art at the time the invention was made would have been motivated to use a mixture of titanium dioxide and zinc oxide with the size of Choulot et al. in the sunscreen composition of Lukenbach et al., with a reasonable expectation of success.

Response to Arguments

Applicants have not argued the merits of the instant rejection separately from the rejection of claims 1, 4, 8, and 13-15 over Lukenbach et al (US Patent 5,980,871). Accordingly, claim 9 stands rejected for reasons stated above.

7. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lukenbach et al (US Patent 5,980,871) in further view of Kaplan (US Patent 5,989,529).

Claims 10 and 11 of the claimed invention are drawn to an oily dispersion of pigments for protection against UV radiation, characterized by comprising, in a single oily base, zinc oxide and titanium dioxide added in the form of a powder, wherein the two pigments are dispersed in a single oily dispersing vehicle and the dispersion further comprises a single emollient vehicle, and wherein the dispersing vehicle is selected from the group consisting of polyethyleneglycol and silicone esters, particularly dipolyhydroxy stearate PEG 30.

Lukenbach et al. teach that the carrier oil should be selected from the group of polyether interrupted fatty acid esters (col. 5, lines 65-66).

Kaplan teaches that PEG 30 dipolyhydroxystearate may be advantageously used to permit the formulation of "an improved oil-in-water sunscreen formulation having improved stability, low viscosity and cosmetic elegancy." (col. 1, lines 40-46).

Lukenbach et al. differ from the claimed invention in claims 10 and 11 because they do not specifically teach that the oil is polyethyleneglycol esters or dipolyhydroxy stearate PEG 30.

However, since Kaplan teaches that PEG 30 dipolyhydroxystearate may be advantageously used to permit the formulation of "an improved oil-in-water sunscreen formulation having improved stability, low viscosity and cosmetic elegancy", and since both compositions are drawn to sunscreen formulations, a person having ordinary skill in the art at the time the invention was made would have been motivated to choose dipolyhydroxy stearate PEG 30 as the oil in the sunscreen composition of Lukenbach et al., with a reasonable expectation of success.

Response to Arguments

Applicants have not argued the merits of the instant rejection separately from the rejection of claims 1, 4, 8, and 13-15 over Lukenbach et al (US Patent 5,980,871). Accordingly, claims 10 and 11 stand rejected for reasons stated above.

8. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lukenbach et al (US Patent 5,980,871) in further view of Liu et al (US Patent 5,916,544).

The instant invention is drawn to an oily dispersion of pigments for protection against UV radiation, characterized by comprising, in a single oily base, zinc oxide and titanium dioxide added in the form of a powder, wherein the two pigments are dispersed in a single oily dispersing vehicle and the dispersion further comprises a single emollient vehicle, and wherein the emollient is selected from the group consisting of isocetyl stearoyl stearate, glycerol tri-2-ethyl hexanoate and propoxylated stearylic alcohol.

Lukenbach et al. teach that the emollient may be "a conventional emollient known to those of ordinary skill in the art as useful in sunscreen products, such as...synthetic emollients such as fatty acid esters and the like" (see col. 6, lines 14-19).

Liu et al. teach that Ceraphyl 791 (isocetyl stearoyl stearate) is known to be used as an emollient in sunscreen compositions with titanium dioxide and zinc oxide (for example, see Examples 18 and 19, col. 6, lines 63-64 and col. 8, lines 20-21).

Lukenbach et al. differ from the claimed invention in claim 12 because they do not specifically teach that the emollient is isocetyl stearoyl stearate, glycerol tri-2-ethyl hexanoate, or propoxylated stearylic alcohol.

However, since Liu et al. teach that Ceraphyl 791 (isocetyl stearoyl stearate) is known to be used as an emollient in sunscreen compositions with titanium dioxide and zinc oxide, and since both compositions are sunscreen compositions, a person having ordinary skill in the art at the time the invention was made would have been motivated

to choose isocetyl stearoyl stearate as the fatty acid ester emollient in the composition of Lukenbach, with a reasonable expectation of success.

Response to Arguments

Applicants have not argued the merits of the instant rejection separately from the rejection of claims 1, 4, 8, and 13-15 over Lukenbach et al (US Patent 5,980,871). Accordingly, claim 12 stands rejected for reasons stated above.

9. Claims 1, 2, 4, 8, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gonzalez et al (US Patent 6,440,402) in view of SaNogueira et al (US Patent 6,830,746) and Cole et al (US Patent 5,340,567).

The claimed invention is delineated above (see paragraph 2).

Gonzalez et al teach sunscreen compositions wherein the sunscreen agents may be a combination of known sunscreens, including titanium dioxide and zinc oxide (col. 2, lines 31-51). The sunscreen actives may be present at up to about 70 wt %, preferably from about 0.05 wt % to about 50 wt % (col. 2, lines 53-56). Suitable vehicles for the sunscreen agents include oils (col. 3, lines 63-65). The composition may further include emollients (col. 4, lines 42).

Gonzalez et al do not specifically teach the combination of titanium dioxide and zinc oxide in the amounts specified by claim 1.

SaNogueira et al teach that higher amounts of sunscreen agents, including combinations of titanium dioxide and zinc oxide, result in higher SPF values (col. 2, lines 33-62).

Cole et al teach that, when titanium dioxide and zinc oxide are used in a preferable weight ratio of 1:8 to 3:1, they act as a synergistic combination with respect to SPF values (col. 4, lines 62-66).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to use titanium dioxide and zinc oxide in amounts specified in claim 1 of the claimed invention in the composition taught by Gonzalez et al; thus arriving at the claimed invention. One skilled in the art would be motivated to do so because higher amounts of sunscreen agents (e.g., where the total amount of sunscreen approaches 50%) result in greater functionality of the sunscreen agents (i.e., higher SPF values) as taught by SaNogueira et al. Furthermore, the weight ratio of 3:1 results in a synergistic combination and therefore is preferred, as taught by Cole et al. Therefore, the amounts of titanium dioxide and zinc oxide would be comparable to or overlap those of the claimed invention; for example, at a weight ratio of 3:1 (as taught by Cole) and a weight amount of 0.05-50% (as taught by Gonzalez et al), the amount of titanium dioxide would be 0.0375-37.5%, and the amount of zinc oxide would be 0.0125-12.5%; these amounts overlap those of the claimed invention. One skilled in the art would be motivated to manipulate the amounts of titanium dioxide and zinc oxide from within said ranges by routine experimentation, in order to optimize the SPF values of the resultant composition. One would reasonably expect success from the use of titanium dioxide and zinc oxide in the composition taught by Gonzalez et al in higher amounts as taught by SaNogueira et al and preferred weight ratios as taught by Cole et al because all of the references are drawn to sunscreen compositions.

Regarding claim 2, Cole et al teach that the weight ratio of titanium dioxide to zinc oxide of 3:1 results in a synergistic combination with respect to SPF values (see col. 4, lines 63-66).

Regarding claim 4, Gonzalez et al teach that the total concentration of sunscreen agents, including the combination of titanium dioxide and zinc oxide, is preferably 0.05 to 50 wt% (col. 2, lines 53-56). This range encompasses that of the claimed invention, and one skilled in the art would be motivated to select amounts of sunscreen agents from within said range by routine experimentation, in order to optimize the SPF value of the resultant composition.

Regarding claim 8, Gonzalez et al do not specifically teach an amount of zinc oxide in the range of 5 to 10% by weight. However, Cole et al teach that a preferred weight ratio of titanium dioxide to zinc oxide of 3:1 results in a synergistic combination with respect to SPF values, and SaNogueira et al teach that higher amounts of sunscreen agents result in higher SPF values. Therefore, the resultant amount of zinc oxide would be comparable to or overlap that of the claimed invention, and one skilled in the art would be motivated to select amounts of zinc oxide from the preferred ranges by routine experimentation, in order to optimize the SPF values of the resultant composition.

Regarding claim 15, Gonzalez et al teach that the compositions are topical sunscreen compositions (abstract) and may other cosmetically acceptable ingredients (col. 4, lines 38-49).

Response to Arguments

10. Applicant's arguments filed 5/12/09 have been fully considered but they are not persuasive.

Applicants argue that Gonzalez specifically mentions 22 sunscreen agents, "only briefly mentions" TiO2 and ZnO in passing, does not exemplify a composition containing either one of TiO2 and ZnO, and describes that the agents may be present in a broad range up to 70 weight percent. Applicants argue that a composition containing 30 to 35% TiO2 and/or 2 to 25% ZnO is not disclosed or suggested by Gonzalez.

This argument is not persuasive because Applicants are treating the references individually, and not considering the rejection as a whole. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant rejection, Cole teaches that titanium dioxide and zinc oxide in certain weight ratios (preferably 1:8 to 3:1) acts as a synergistic combination with respect to SPF values. Therefore, one skilled in the art would be motivated to select titanium dioxide and zinc oxide from the list of identified, predictable choices of Gonzalez, with the expected result of producing a sunscreen composition. Additionally, the amounts of titanium dioxide and zinc oxide would be comparable to or overlap those of the claimed invention; for example, at a weight ratio of 3:1 (as taught by Cole) and a weight amount of 0.05-50% (as taught by Gonzalez et al), the amount of titanium dioxide would be 0.0375-37.5%, and the amount of zinc oxide would be 0.0125-12.5%; these amounts

overlap those of the claimed invention. One skilled in the art would be motivated to manipulate the amounts of titanium dioxide and zinc oxide from within said ranges by routine experimentation, in order to optimize the SPF values of the resultant composition.

Applicants also argue that Cole teaches that the total amount of pigments should be 4 to 25% since less than 4% and more than 25% "would not render good results", and therefore someone skilled in the art would not think about using the pigment proportions used in Cole (3:1) when higher amounts of pigments were employed.

This argument is not persuasive because the teachings of Cole are relied upon merely to show that certain weight ratios of titanium dioxide and zinc oxide result in synergistic combinations with respect to SPF values. Additionally, Cole does not teach that amounts of pigments of more than 25% "would not render good results", as Applicants assert, but rather that, at amounts above 25%, "processing and economic factors come into consideration" (see col. 4, lines 59-61). Thus, Cole does not teach away from using its weight ratios at other concentrations, and thus one skilled in the art would be motivated to use the weight ratios of Cole in the composition of Gonzalez with the expected result of a "synergistic combination with respect to SPF values", as taught by Cole.

Therefore, it is the Examiner's position that the claims are rendered obvious.

Claim Objections

11. The objection to claims 14 and 15 is withdrawn in view of Applicant's amendments to claims 14 and 15.

Conclusion

No claims are allowed at this time.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BARBARA FRAZIER whose telephone number is

(571)270-3496. The examiner can normally be reached on Monday-Thursday 9am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BSF

/Sharmila Gollamudi Landau/

Supervisory Patent Examiner, Art Unit 1611